K120401

510(k) Summary

OCT 5 2012

Summary of 510(k) Safety and Effectiveness

Submitted By:	Alliance Partners, LLC 121 Interpark Blvd, #601 San Antonio, TX 78216
Date:	July 11, 2012
Contact Person:	Jennifer Palinchik Development and Regulatory Consultant
Contact Telephone:	(440) 933-8850
Device Trade Name:	Alamo T
Device Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Lumbar
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	888.3080
Product Code:	MAX
Predicate Device:	Globus Medical Signature TLIF Spacer (K072970) Genesys Spine Interbody Fusion System (K103034)

Device Description:

The Alamo T is used for spinal fusion surgery to provide support and structural stability at the fusion site following discectomy. The device is manufactured from PEEK Optima® LT1 per ASTM F2026 and includes tantalum markers per ASTM F560 for radiographic visualization.

The device footprint has a hollow centre to accommodate bone graft to facilitate bone integration and fusion between the end plates from a transforaminal (TLIF) surgical approach. The device is available in various heights to accommodate variability among patients and the inferior and superior surfaces are designed with ridges to improve fixation and stability and prevent back out and migration.

Intended Use:

The Alamo T is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via a transforaminal approach.

Substantial Equivalence Information:

The design features, material, and indications for use of the Alamo T device are substantially equivalent to the predicate devices listed above. The safety and effectiveness is adequately supported by the substantial equivalence, material information, and analysis data provided within this Premarket Notification.

Item	Alamo T	Globus TLIF Spacer	Genesys TLIF System
Product Code	MAX	MAX	MAX, ODP, MQP
Classification Name	Intervertebral Body Fusion Device	Same	Same
Intended Use	degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1)	Same	Same. Also intended for vertebral body replacement
Footprint	Blocks have one length and width, and a variety of heights with axial and lateral openings for bone graft and rows of teeth. No pivoting mechanism	Blocks in a variety of lengths, widths, and heights with axial and lateral openings for bone graft and rows of teeth. Pivoting mechanism for controlled articulation during insertion	Blocks have one length and width, and a variety of heights with axial and lateral openings for bone graft and rows of teeth. No pivoting mechanism
Graft Opening	Large axial graft window	Same plus anterior graft windows	Same
Teeth to prevent migration	Located on superior and inferior surfaces. Pyramid pattern	Same	Same, but linear pattern
Radiographic markers	Yes	Yes	Yes
Axial Footprint dimensions	10 x 28mm	10 x 28mm and 11 x 33mm	14 x 35mm
Device Height	8mm-14mm (1mm increments)	7mm-17mm (1mm increments), excluding 14mm	6mm-15mm (1mm increments)
Material	PEEK Optima LT1 and Tantalum (markers)	Same	Same

Mechanical Testing:

Performance testing was conducted via the following mechanical tests per ASTM F2077 and F2267 using the worst case device: Static Compression, Dynamic Compression, Subsidence, and Expulsion. The device functioned as intended and the performance results show that the Alamo T is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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OCT 5 2012

Re: K120401
Trade/Device Name: Alamo T
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 26, 2012
Received: September 27, 2012

Dear Ms. Palinchik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120401

Device Name: Alamo T

Indications for Use:

The Alamo T is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via a transforaminal approach.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120401